

Amendment and Response - Under 37 C.F.R. §1.116 - Expedited Examining Procedure Page 2 of 6
Serial No.: 09/641,801
Confirmation No.: 5388
Filed: August 17, 2000
For: USES OF COLOSTRININ, CONSTITUENT PEPTIDES THEREOF, AND ANALOGS THEREOF FOR
INDUCING CYTOKINES

Remarks

The Office Action mailed March 5, 2003 has been received and reviewed. Claim 20 having been amended to correct a typographical error, the pending claims are claims 1-4, 6-9, 11, 13-35, and 37-39. Reconsideration and withdrawal of the rejections are respectfully

Examiner Interview

A telephonic Examiner's Interview was held on May 20, 2003 between the Applicants' representatives, Supervisory Patent Examiner Kunz and Patent Examiner Nichols, in which the outstanding restriction requirement was discussed. It was agreed upon that claims 20 and 29 qualify as linking claims. With the identification of allowable claims drawn to the elected species SEQ ID NO:1, non-elected species SEQ ID NO:2 -34 will be rejoined and examined upon indication of otherwise allowable subject matter. Examiners Kunz and Nichols are thanked for the courtesy of this telephonic interview.

Traverse of the Restriction Requirement

In response to the Restriction Requirement mailed June 17, 2002, Applicants elected, with traverse, Group 1 (claims 1-35), drawn to methods of contacting cells with SEQ ID NO:1 (Response to Restriction Requirement, filed July 17, 2002). Applicants continue to traverse this Restriction Requirement, noting that claims 20 and 29 are linking claims. Accordingly, the Examiner's restriction appears to be more appropriately an election of species with respect to specific sequences. See MPEP 809.02. Thus, Applicants traverse on the grounds that the generic (linking) claims 20 and 29 include sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the Examiner. Applicants also request rejoinder and that the requirement be withdrawn upon the finding of an allowable genus.

Amendment and Response - Under 37 C.F.R. §1.116 - Expedited Examining Procedure Page 3 of 6
Serial No.: 09/641,801
Confirmation No.: 5388
Filed: August 17, 2000
For: USES OF COLOSTRININ, CONSTITUENT PEPTIDES THEREOF, AND ANALOGS THEREOF FOR
INDUCING CYTOKINES

Objection to the Claims

The Examiner objected to claims 20-35 for the recitation of the non-elected inventions SEQ ID NO's 2-34. In view of the Applicants' request for the rejoinder of SEQ ID NO:2-34, discussed above, Applicants respectfully submit that this objection to the claims is moot. Withdrawal of this objection is respectfully requested.

The 35 U.S.C. §102 Rejection over Inglot et al.

The Examiner has maintained the rejection of claims 1-4 and 6-9 under 35 U.S.C. § 102 as being anticipated by Inglot et al. Specifically, the Examiner asserted that the NP peptide disclosed by Inglot anticipates the active analog, "wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to SEQ ID NO:1" of claims 1-4 and 6-9. In maintaining this rejection, the Examiner asserted that as the NP peptide of Inglot et al. is nine residues long and as the peptide of SEQ ID NO:1 is 7 residues long, "therefore NP is 77% structurally similar based on length, a structural characteristic, thus meeting the limitations of claims 1-4 and 6-9.

Applicants respectfully traverse this rejection. As defined on page 11, line 29 to page 12, line 2 of the specification, "[s]tructural similarity is generally determined by aligning the residues of two amino acid sequences to optimize the number of identical amino acids residues along the lengths of their sequences; gaps in either or both sequences are permitted in making the alignment in order to optimize the number of identical amino acids, although the amino acids in each sequence must nonetheless remain in their proper order." Thus, length alone does not establish "structural similarity." Rather, structural similarity is based on whether-or-not amino acid residues are identical, when compared one to another.

Applicants respectfully submit that the NP peptide of Inglot et al. does not have "at least about 70 percent structural similarity to SEQ ID NO:1." Thus, claims 1-4 and 6-9 are not anticipated by Inglot et al. and withdrawal of this rejection of the claims under 35 U.S.C. § 102 is respectfully requested.

Amendment and Response - Under 37 C.F.R. §1.116 - Expedited Examining Procedure Page 4 of 6
Serial No.: 09/641,801
Confirmation No.: 5388
Filed: August 17, 2000
For: USES OF COLOSTRININ, CONSTITUENT PEPTIDES THEREOF, AND ANALOGS THEREOF FOR
INDUCING CYTOKINES

The 35 U.S.C. §102 Rejection over Janusz et al.

The Examiner has maintained the rejection of claims 11 and 13-35 under 35 U.S.C. § 102 as being anticipated by Janusz et al. (WO 98/14473). This rejection is respectfully traversed.

Claims 11 and 13-19 are drawn to an immunological regulator, "wherein the immunological regulator comprises MQPPPLP (SEQ ID NO:1), an active analog thereof, and combinations thereof, wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to SEQ ID NO:1." Claims 27 and 34 are drawn to a leukocyte regulator that is selected from the group of SEQ ID NO:1-34, "an active analog thereof, and combinations thereof; wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin, which are selected from the group of SEQ ID NO:1 through SEQ ID NO:34. Claims 28 and 35 are drawn to a leukocyte regulator selected from the group consisting of SEQ ID NO:1-8, SEQ ID NO:18-20, SEQ ID NO:22, and combinations thereof.

Applicants respectfully submit that Janusz et al. do not teach immunological regulators or leukocyte regulators that are the same as those claimed. As previously discussed, "structural similarity" is not determined by the mere comparison of length alone. Thus, the NP peptide of Janusz et al. does not have "at least about 70 percent structural similarity to SEQ ID NO:1," and claims 11, 13-19, 27, 28, 34, and 35 are not anticipated by Janusz et al.

Claims 20-28 are drawn to a "method for modulating leukocyte proliferation . . . comprising contacting leukocytes with a leukocyte regulator selected from the group of colostrinin, a constituent peptide thereof, an active analog thereof, and combinations thereof, *under conditions effective to change the number of leukocytes*" and claims 29-35 are drawn to a "method for modulating leukocyte proliferation in a patient . . . comprising administering to the patient a leukocyte regulator selected from the group of colostrinin, a constituent peptide thereof, an analog thereof, and combinations thereof, *under conditions effective to change the*

Amendment and Response - Under 37 C.F.R. §1.116 - Expedited Examining Procedure Page 5 of 6
Serial No.: 09/641,801
Confirmation No.: 5388
Filed: August 17, 2000
For: USES OF COLOSTRININ, CONSTITUENT PEPTIDES THEREOF, AND ANALOGS THEREOF FOR
INDUCING CYTOKINES

number of leukocytes." Claims 26 and 33 are further limited to "wherein the leukocyte regulator is a constituent peptide of colostrinin," and claims 27, 28, 34 and 35 are drawn leukocyte regulators selected from specific SEQ ID NO's, and active analogs thereof.

Applicants respectfully submit that Janusz et al. do not teach the claimed methods of modulating leukocyte proliferation, wherein modulating leukocyte proliferation is a change in the number of leukocytes. The Examiner asserted that "[o]nce administered, colostrinin would inherently and necessarily have caused an increase in leukocytes." And, citing Chapter 10 "Cytokines" of Elgert's "Immunology: Understanding the Immune System" textbook (pp. 199-217), the Examiner further asserted that "'growth, maturation, and differentiation' include proliferation or an increase in cell number" (see p. 8 of the Office Action mailed March 5, 2003). Applicants respectfully disagree.

Applicants are unable to locate within the cited pages of Elgert's Immunology textbook any statements that substantiate the Examiner's assertions. The Examiner is basing this rejection on the doctrine of inherency. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." M.P.E.P §2112 (emphasis in original). It is respectfully submitted that the Examiner has not met his burden of providing a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the cited documents.

Applicants respectfully submit that Janusz et al. does not teach a method of modulating leukocyte proliferation comprising contacting leukocytes with colostrinin under conditions effective to change the number of leukocytes and, thus, claims 20-35 are not anticipated by Janusz et al.

For the reasons discussed above, claims 11 and 13-35 are not anticipated by Janusz et al. Withdrawal of this rejection of the claims under 35 U.S.C. § 102 is respectfully requested.

Amendment and Response - Under 37 C.F.R. §1.116 - Expedited Examining Procedure Page 6 of 6
Serial No.: 09/641,801
Confirmation No.: 5388
Filed: August 17, 2000
For: USES OF COLOSTRININ, CONSTITUENT PEPTIDES THEREOF, AND ANALOGS THEREOF FOR
INDUCING CYTOKINES

Summary

It is respectfully submitted that the pending claims 1-4, 6-9, 11, 13-35, and 37-39 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
Stanton et al.

By
Mueeting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
Phone: (612) 305-1220
Facsimile: (612) 305-1228
Customer Number 26813



26813

PATENT TRADEMARK OFFICE

June 5, 2003
Date

By:

Ann M. Mueeting
Ann M. Mueeting
Reg. No. 33,977
Direct Dial (612)305-1217

CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Assistant Commissioner for Patents, Mail Stop AF, Alexandria, VA 22313-1450, on this 5th day of June, 2003, at 5:15 pm (Central Time).

By:

Name:

SPENCER OLSON

**APPENDIX A - SPECIFICATION/CLAIM AMENDMENTS
INCLUDING NOTATIONS TO INDICATE CHANGES MADE**

Serial No.: 09/641,801

Docket No.: 265.00230101

Amendments to the following are indicated by underlining what has been added and bracketing what has been deleted.

In the Claims

For convenience, all pending claims are shown below.

1. A method of inducing a cytokine in a cell, the method comprising contacting the cell with an immunological regulator under conditions effective to induce a cytokine, wherein the immunological regulator comprises MQPPPLP (SEQ ID NO:1), an active analog thereof, and combinations thereof, wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to SEQ ID NO:1.
2. The method of claim 1 wherein the cell is present in a cell culture, a tissue, an organ, or an organism.
3. The method of claim 1 wherein the cell is a mammalian cell.
4. The method of claim 3 wherein the cell is a human cell.
6. A method for modulating an immune response in a cell, the method comprising contacting the cell with an immunological regulator under conditions effective to induce a cytokine, wherein the immunological regulator comprises MQPPPLP (SEQ ID NO:1), an active analog thereof, and combinations thereof, wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to SEQ ID NO:1.

Amendment and Response - Appendix A

Page 2-A

Applicant(s): Stanton et al.

Serial No.: 09/641,801

Filed: August 17, 2000

**For: USES OF COLOSTRININ, CONSTITUENT PEPTIDES THEREOF, AND ANALOGS THEREOF FOR
INDUCING CYTOKINES**

7. The method of claim 6 wherein the cell is present in a cell culture, a tissue, an organ, or an organism.
8. The method of claim 6 wherein the cell is a mammalian cell.
9. The method of claim 8 wherein the cell is a human cell.
11. A method for modulating an immune response in a patient, the method comprising administering to the patient an immunological regulator under conditions effective to induce a cytokine, wherein the immunological regulator comprises MQPPPLP (SEQ ID NO:1), an active analog thereof, and combinations thereof, wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to SEQ ID NO:1.
13. The method of claim 11 wherein the immunological regulator is administered as part of a dietary supplement.
14. The method of claim 11 wherein the immunological regulator is administered topically.
15. The method of claim 11 wherein the patient is an animal.
16. The method of claim 15 wherein the patient is a human.
17. The method of claim 11 wherein the immune response is a specific immune response.
18. The method of claim 11 wherein the immune response is a nonspecific immune response.

Amendment and Response - Appendix A

Page 3-A

Applicant(s): Stanton et al.

Serial No.: 09/641,801

Filed: August 17, 2000

For: USES OF COLOSTRININ, CONSTITUENT PEPTIDES THEREOF, AND ANALOGS THEREOF FOR
INDUCING CYTOKINES

19. The method of claim 11 wherein the immune response is the interferon response or antibody production.
20. [Amended] A method for modulating leukocyte proliferation, the method comprising contacting leukocytes with a leukocyte regulator selected from the group of colostrinin, a constituent peptide thereof, an active analog thereof, and combinations thereof, under conditions effective to change the number of leukocytes; wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin, which are selected from the group of SEQ ID NO:1 through SEQ ID NO:34.
21. The method of claim 20 wherein the leukocytes are present in a cell culture or an organism.
22. The method of claim 20 wherein the leukocytes are mammalian cells.
23. The method of claim 22 wherein the leukocytes are human cells.
24. The method of claim 22 wherein the leukocytes are increased in number.
25. The method of claim 24 wherein the leukocytes are differentiated.
26. The method of claim 22 wherein the leukocyte regulator is a constituent peptide of colostrinin.
27. The method of claim 26 wherein the leukocyte regulator is selected from the group of MQPPPLP (SEQ ID NO:1), LQTPQPLLQVMMEPQGD (SEQ ID NO:2),

Amendment and Response - Appendix A

Page 4-A

Applicant(s): Stanton et al.

Serial No.: 09/641,801

Filed: August 17, 2000

For: USES OF COLOSTRININ, CONSTITUENT PEPTIDES THEREOF, AND ANALOGS THEREOF FOR INDUCING CYTOKINES

DQPPDVEKPDLPFQVQS (SEQ ID NO:3), LFFFLPVNVLP (SEQ ID NO:4),
DLEMPVLPVEPFFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6),
VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFKPKLKEVFPFP (SEQ ID NO:8), VVMEV
(SEQ ID NO:9), SEQP (SEQ ID NO:10), DKE (SEQ ID NO:11), FPPPK (SEQ ID NO:12),
DSQPPV (SEQ ID NO:13), DPPPPQS (SEQ ID NO:14), SEEMP (SEQ ID NO:15), KYKLQPE
(SEQ ID NO:16), VLPPNVG (SEQ ID NO:17), VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL
(SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), LQPEIMGVPKVKETMVPK (SEQ ID
NO:21), HKEMPFKYPVEPFTESQ (SEQ ID NO:22), SLTLTDVEKLHLPLPLVQ (SEQ ID
NO:23), SWMHQPP (SEQ ID NO:24), QLPPTVMFP (SEQ ID NO:25), PQSVLS (SEQ ID
NO:26), LSQPKVLPVPQKAVPQRDMPIQ (SEQ ID NO:27), AFLLYQE (SEQ ID NO:28),
RGFPILV (SEQ ID NO:29), ATFNRYQDDHGEEILKSL (SEQ ID NO:30), VESYVPLFP
(SEQ ID NO:31), FLLYQEPVLGPVR (SEQ ID NO:32), LNF (SEQ ID NO:33), and
MHQPPQPLPPTVMFP (SEQ ID NO:34), an active analog thereof, and combinations thereof;
wherein the active analog comprises a peptide having an amino acid sequence with at least about
15 percent proline and having at least about 70 percent structural similarity to one or more
constituent peptides of colostrinin, which are selected from the group of SEQ ID NO:1 through
SEQ ID NO:34.

28. The method of claim 27 wherein the leukocyte regulator is selected from the group of
MQPPPLP (SEQ ID NO:1), LQTPQPLLQVMMEPQGD (SEQ ID NO:2),
DQPPDVEKPDLPFQVQS (SEQ ID NO:3), LFFFLPVNVLP (SEQ ID NO:4),
DLEMPVLPVEPFFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6),
VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFKPKLKEVFPFP (SEQ ID NO:8), YPFTGPIPN
(SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20),
HKEMPFKYPVEPFTESQ (SEQ ID NO:22), and combinations thereof.

Amendment and Response - Appendix A

Page 5-A

Applicant(s): Stanton et al.

Serial No.: 09/641,801

Filed: August 17, 2000

For: USES OF COLOSTRININ, CONSTITUENT PEPTIDES THEREOF, AND ANALOGS THEREOF FOR INDUCING CYTOKINES

-
29. A method for modulating leukocyte proliferation in a patient, the method comprising administering to the patient a leukocyte regulator selected from the group of colostrinin, a constituent peptide thereof, an analog thereof, and combinations thereof, under conditions effective to change the number of leukocytes; wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin, which are selected from the group of SEQ ID NO:1 through SEQ ID NO:34.
30. The method of claim 29 wherein the patient is a human.
31. The method of claim 29 wherein the leukocytes are increased in number.
32. The method of claim 31 wherein the leukocytes are differentiated.
33. The method of claim 29 wherein the leukocyte regulator is a constituent peptide of colostrinin.
34. The method of claim 33 wherein the leukocyte regulator is selected from the group of MQPPPLP (SEQ ID NO:1), LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDQLQPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFKPKLKEVFPFP (SEQ ID NO:8), VVMEV (SEQ ID NO:9), SEQP (SEQ ID NO:10), DKE (SEQ ID NO:11), FPPPK (SEQ ID NO:12), DSQPPV (SEQ ID NO:13), DPPPPQS (SEQ ID NO:14), SEEMP (SEQ ID NO:15), KYKLQPE (SEQ ID NO:16), VLPPNVG (SEQ ID NO:17), VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), LQPEIMGVPKVKETMVPK (SEQ ID NO:21), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), SLTLTDVEKLHLPLPLVQ (SEQ ID NO:23), LQTPQPLLQVMMEPQGD (SEQ ID NO:24), DQPPDVEKPDQLQPFQVQS (SEQ ID NO:25), LFFFLPVVNVLP (SEQ ID NO:26), DLEMPVLPVEFPFV (SEQ ID NO:27), MPQNFYKLPQM (SEQ ID NO:28), VLEMKFPPPPQETVT (SEQ ID NO:29), LKPFKPKLKEVFPFP (SEQ ID NO:30), VVMEV (SEQ ID NO:31), SEQP (SEQ ID NO:32), DKE (SEQ ID NO:33), FPPPK (SEQ ID NO:34), DSQPPV (SEQ ID NO:35), DPPPPQS (SEQ ID NO:36), SEEMP (SEQ ID NO:37), KYKLQPE (SEQ ID NO:38), VLPPNVG (SEQ ID NO:39), VYPFTGPIPN (SEQ ID NO:40), SLPQNILPL (SEQ ID NO:41), TQTPVVVPPF (SEQ ID NO:42), LQPEIMGVPKVKETMVPK (SEQ ID NO:43), HKEMPFPKYPVEPFTESQ (SEQ ID NO:44), SLTLTDVEKLHLPLPLVQ (SEQ ID NO:45).

Amendment and Response - Appendix A

Page 6-A

Applicant(s): Stanton et al.

Serial No.: 09/641,801

Filed: August 17, 2000

For: USES OF COLOSTRININ, CONSTITUENT PEPTIDES THEREOF, AND ANALOGS THEREOF FOR INDUCING CYTOKINES

NO:23), SWMHQPP (SEQ ID NO:24), QLPPTVMFP (SEQ ID NO:25), PQSVLS (SEQ ID NO:26), LSQPKVLPVPQKAVPQRDMPIQ (SEQ ID NO:27), AFLLYQE (SEQ ID NO:28), RGPFPILV (SEQ ID NO:29), ATFNRYQDDHGEEILKSL (SEQ ID NO:30), VESYVPLFP (SEQ ID NO:31), FLLYQEPVLGPVR (SEQ ID NO:32), LNF (SEQ ID NO:33), and MHQPPQPLPPTVMFP (SEQ ID NO:34), an active analog thereof, and combinations thereof; wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin, which are selected from the group of SEQ ID NO:1 through SEQ ID NO:34.

35. The method of claim 34 wherein the leukocyte regulator is selected from the group of MQPPPLP (SEQ ID NO:1), LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPEP (SEQ ID NO:8), VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), and combinations thereof.

37. A method of inducing a cytokine in a cell, the method comprising contacting the cell with an immunological regulator under conditions effective to induce a cytokine, wherein the immunological regulator is a constituent peptide of colostrinin selected from the group consisting of LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLPFQVQS (SEQ ID NO:3), LFFFLPVVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPEP (SEQ ID NO:8), VVMEV (SEQ ID NO:9), SEQP (SEQ ID NO:10), DKE (SEQ ID NO:11), FPPPK (SEQ ID NO:12), DSQPPV (SEQ ID NO:13), DPPPPQS (SEQ ID NO:14), SEEMP (SEQ ID NO:15), KYKLQPE (SEQ ID NO:16), VLPPNVG (SEQ ID

Amendment and Response - Appendix A

Page 7-A

Applicant(s): Stanton et al.

Serial No.: 09/641,801

Filed: August 17, 2000

For: USES OF COLOSTRININ, CONSTITUENT PEPTIDES THEREOF, AND ANALOGS THEREOF FOR INDUCING CYTOKINES

NO:17), VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), LQPEIMGVPKVKETMVPK (SEQ ID NO:21), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), SLTLTDVEKLHLPLPLVQ (SEQ ID NO:23), SWMHQPP (SEQ ID NO:24), QPLPPTVMFP (SEQ ID NO:25), PQSVLS (SEQ ID NO:26), LSQPKVLPVPQKAVPQRDMPIQ (SEQ ID NO:27), AFLLYQE (SEQ ID NO:28), RGPFPILV (SEQ ID NO:29), ATFNRYQDDHGEEILKSL (SEQ ID NO:30), FLLYQEPVLGPVR (SEQ ID NO:32), LNF (SEQ ID NO:33), and MHQPPQPLPPTVMFP (SEQ ID NO:34), an active analog thereof, and combinations thereof, wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to a one or more constituent peptides of colostrinin which are selected from the group of SEQ ID NO:2-30 and 32-34.

38. A method for modulating an immune response in a cell, the method comprising contacting the cell with an immunological regulator under conditions effective to induce a cytokine, wherein the immunological regulator is a constituent peptide of colostrinin selected from the group consisting of LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLPFQVQS (SEQ ID NO:3), LFFFLPVNVLP (SEQ ID NO:4), DLEMPVLPVEPFPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPFPKLKVEVFPFP (SEQ ID NO:8), VVMEV (SEQ ID NO:9), SEQP (SEQ ID NO:10), DKE (SEQ ID NO:11), FPPPK (SEQ ID NO:12), DSQPPV (SEQ ID NO:13), DPPPQS (SEQ ID NO:14), SEEMP (SEQ ID NO:15), KYKLQPE (SEQ ID NO:16), VLPPNVG (SEQ ID NO:17), VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), LQPEIMGVPKVKETMVPK (SEQ ID NO:21), HKEMPFPKYPVEPFTESQ (SEQ ID NO:22), SLTLTDVEKLHLPLPLVQ (SEQ ID NO:23), SWMHQPP (SEQ ID NO:24), QPLPPTVMFP (SEQ ID NO:25), PQSVLS (SEQ ID NO:26), LSQPKVLPVPQKAVPQRDMPIQ (SEQ ID NO:27), AFLLYQE (SEQ ID NO:28), RGPFPILV (SEQ ID NO:29), ATFNRYQDDHGEEILKSL (SEQ ID NO:30),

Amendment and Response - Appendix A

Page 8-A

Applicant(s): Stanton et al.

Serial No.: 09/641,801

Filed: August 17, 2000

For: USES OF COLOSTRININ, CONSTITUENT PEPTIDES THEREOF, AND ANALOGS THEREOF FOR INDUCING CYTOKINES

FLLYQEPVLGPVR (SEQ ID NO:32), LNF (SEQ ID NO:33), and MHQPPQPLPPTVMFP (SEQ ID NO:34), an active analog thereof, and combinations thereof, wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin which are selected from the group of SEQ ID NO:2-30 and 32-34.

39. A method for modulating an immune response in a patient, the method comprising administering to the patient an immunological regulator under conditions effective to induce a cytokine, wherein the immunological regulator is a constituent peptide of colostrinin selected from the group consisting of LQTPQPLLQVMMEPQGD (SEQ ID NO:2), DQPPDVEKPDLPFQVQS (SEQ ID NO:3), LFFFLPVNVLP (SEQ ID NO:4), DLEMPVLPVEPPFV (SEQ ID NO:5), MPQNFYKLPQM (SEQ ID NO:6), VLEMKFPPPPQETVT (SEQ ID NO:7), LKPPFKLKVEVFPPF (SEQ ID NO:8), VVMEV (SEQ ID NO:9), SEQP (SEQ ID NO:10), DKE (SEQ ID NO:11), FPPPK (SEQ ID NO:12), DSQPPV (SEQ ID NO:13), DPPPPQS (SEQ ID NO:14), SEEMP (SEQ ID NO:15), KYKLOPE (SEQ ID NO:16), VLPPNVG (SEQ ID NO:17), VYPFTGPIPN (SEQ ID NO:18), SLPQNILPL (SEQ ID NO:19), TQTPVVVPPF (SEQ ID NO:20), LQPEIMGVPKVKETMVPK (SEQ ID NO:21), HKEMPPFKYPVEPFTESQ (SEQ ID NO:22), SLTLTDVEKLHLPLLVQ (SEQ ID NO:23), SWMHQPP (SEQ ID NO:24), QPLPPTVMFP (SEQ ID NO:25), PQSVLS (SEQ ID NO:26), LSQPKVLPVPQKAVPQRDMPIQ (SEQ ID NO:27), AFLLYQE (SEQ ID NO:28), RGPFPILV (SEQ ID NO:29), ATFNRYQDDHGEEILKSL (SEQ ID NO:30), FLLYQEPVLGPVR (SEQ ID NO:32), LNF (SEQ ID NO:33), and MHQPPQPLPPTVMFP (SEQ ID NO:34), an active analog thereof, and combinations thereof, wherein the active analog comprises a peptide having an amino acid sequence with at least about 15 percent proline and having at least about 70 percent structural similarity to one or more constituent peptides of colostrinin which are selected from the group of SEQ ID NO:2-30 and 32-34.